

PATIENT

INSTRUCTIONS

For Menicon Z™ (tisilfocon A)

Rigid Gas Permeable Contact Lens

CAUTION: Federal (U.S.A) law restricts this device to sale
by or on the order of a licensed eyecare professional.

Menicon Z™ (tisilfocon A)

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Commonly Used Terms

Cornea	<p>The clear “window” of the eye, permitting light to enter, located in front of the iris and pupil</p> <ul style="list-style-type: none">• Iris – The colored part of the eye which controls the size of the pupil• Pupil – The black round opening surrounded by the iris
Astigmatism	<p>A common vision condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape causing the visual image to be out of focus (blurred)</p>
Presbyopia	<p>The gradual loss of the eye’s ability to change focus from distance to near resulting in a need for additional correction for near tasks such as reading. The effects of presbyopia are generally first noticed after age 40</p>
Disinfect	<p>A process which kills harmful microorganisms (germs) which can cause serious eye infections</p>
Lens Deposits	<p>Particles such as cosmetics, lotions, and protein from the tear film, environmental pollutants, etc., which collect on the lens surface</p>
Extended Wear	<p>Wearing lenses for 24 hours a day, including while sleeping</p>
30 Day Continuous Wear	<p>Extended wear for up to 30 days/29 nights in a row</p>

INTRODUCTION

This booklet explains how to safely use your Menicon Z™ (tisilfocon A) contact lenses. Read it and keep it in a safe place for future reference.

The Menicon Z™ (tisilfocon A) spherical, aspheric, non-prism ballast toric and non-prism ballast multifocal lenses are intended for daily wear or extended wear. Prism ballast toric lenses and prism ballast multifocal lenses are for daily wear use only. The lens color is light blue with an ultraviolet absorber added (Benzotriazol).

WEARING RESTRICTIONS AND INDICATIONS

Menicon Z™ (tisilfocon A) spherical, aspheric, prism ballast toric and prism ballast multifocal lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia, and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

Menicon Z™ (tisilfocon A) spherical, aspheric, non-prism ballast toric and non-prism ballast multifocal lenses are indicated for extended wear (from 1 to 30 days between removals for cleaning and disinfection of the lenses, as recommended by the eyecare professional) for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in non-aphakic persons with non-diseased eyes.

The lens may be prescribed in spherical and aspheric powers ranging from -25.00 D to +25.00 D for daily wear and -25.00 D to +8.00 D for up to 30 days extended wear. Toric lenses are designed to correct up to 5.00 D of astigmatism and multifocal lenses to provide up to +3.00 D of reading add power for up to 30 days extended wear.

The lens may be disinfected using a chemical disinfection system only.

The Menicon Z™ (tisilfocon A) Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eyecare professional.

IF YOU ARE ON A DAILY WEAR SCHEDULE, DO NOT WEAR YOUR MENICON Z™ (TISILFOCON A) CONTACT LENSES WHILE SLEEPING. See **WARNINGS** for information about the relationship between wearing schedule and corneal complications.

Note: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult the eyecare professional for more information.

CONTRAINDICATIONS (Reasons not to use)

DO NOT USE the Menicon Z™ (tisilfocon A) Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions

- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the Menicon Z™ (tisilfocon A) Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated
- Incomplete healing following eye surgery

WARNINGS

- Patients should be advised of the following warnings pertaining to contact lens wear:
- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that you follow your eyecare professional's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Daily wear lenses are not indicated for overnight wear, and should not be worn while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.^{1,2}
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. The long-term risk of microbial keratitis has not been determined for this lens when worn for greater than 7 days extended wear. Postmarketing studies are in progress to evaluate the risk up to 30 days.
- If you experience **eye discomfort**, excessive tearing, vision changes, or redness of the eye, you should **immediately remove lenses** and promptly contact your eyecare professional.
- **UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use your protective UV-absorbing eyewear as directed.**

¹CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37

²New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS

CAUTION: NON-STERILE. CLEAN AND CONDITION LENSES PRIOR TO USE.

Handling Precautions:

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Before leaving your eyecare professional's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses for you.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare professional.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use.

Solution Precautions:

- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may reduce the ability of the lens surface to return to a wettable state.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not heat the cleaning, wetting, and/or soaking solution and lenses. Keep away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Menicon Z™ (tisilfocon A) Contact Lenses.

Lens Wearing Precautions:

- Never wear lenses beyond the period recommended by your eyecare professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Non-Moving) Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eyecare professional.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions:

- Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens manufacturer or your eyecare professional.

Topics to Discuss with Your Eyecare Professional:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.
- Ask your eyecare professional about wearing lenses during water activities and other sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always contact your eyecare professional before using any medicine in your eyes.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, oral contraceptives and motion sickness medications. Always inform your eyecare professional if you experience any problems with your lenses while taking such medications.

Who Should Know That Your Are Wearing Contact Lenses:

- You should inform your doctor (health care professional) about being a contact lens wearer.
- You should always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.

ADVERSE REACTIONS:

The following problems may occur:

- Eyes stinging, burning, itching (irritation) or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling that something is in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above, you should:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact your eyecare professional. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, you should **immediately remove the lenses and consult your eyecare professional.**

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, you **should immediately remove the lenses and contact your eyecare professional** or physician, who must determine the need for examination, treatment or referral without delay (See Important Treatment Information for Adverse Reactions). A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

CLINICAL STUDY

A one-year U.S. pre-marketing clinical study of Menicon Z lenses showed that the product is safe and effective for vision correction for up to 30 days/29 nights of continuous wear.

Six hundred sixty-one (661) subjects were enrolled into a pre-market clinical trial at 24 investigational sites throughout the United States of America. Of those, 630 subjects (317 Menicon Z Test Subjects and 313 Control Subjects) were determined to be evaluable. Of the evaluable subjects, 258 subjects wearing the Menicon Z lens and 210 subjects wearing the Control lens completed the study. The Menicon Z lens was worn for up to 30 days/29 nights of continuous wear and only replaced for cause. The Control lens was worn for up to 7 days/6 nights of continuous wear and scheduled for weekly replacement.

Overall Findings:

Safety: There were no serious adverse events observed during this trial. During the one-year U.S. study, about 0.6% of the 317 subjects experienced an inflammation of the cornea called infiltrative keratitis. In total, about 6.0 % of the subjects experienced one or a combination of moderate or severe events, including superficial corneal changes, corneal swelling or changes to the eyelid lining.

Effectiveness: Wearing schedule – Not everyone reached and maintained the maximum extended wear time of 30 continuous days/29 nights for the entire one-year period. Average wearing times of 22 days or more were reported at 66.5% of all visits after 1 month. 15.5% of wearing time reports were for periods of 8-21 days and 18% of wearing time reports were for periods of less than 8 days.

RISK ANALYSIS

While there are many benefits of wearing contact lenses, sometimes problems occur. You should carefully discuss the benefits and risks of extended wear lenses with your eyecare professional.

With overnight contact lens wear there is an increased risk of developing a serious eye infection, such as a corneal ulcer. A corneal ulcer may develop rapidly and cause eye pain, redness or blurry vision as it progresses. If left untreated, a corneal scar, and in rare cases, loss of vision may result.

In addition, studies have shown that smoking increases the risk of corneal ulcers for contact lens users who wear lenses overnight.

PROCEDURES FOR HANDLING LENSES

1. Preparing the Lens for Wearing

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses.

The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses. Proper hand washing can help to prevent eye infections.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth. Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Handling the Lenses

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or cracks.

3. Placing the Lens on the Eye

Always begin inserting your contact lenses with the same lens to avoid switching your lenses by mistake. Although your contact lens professional will outline a method that is most suitable for you, here's a standard procedure for inserting and removing your lenses that you can always refer to:

- a. Place the lens on the tip of the index finger with your dominant hand, concave side up.
- b. Hold your eyelids wide apart with the thumb and index finger of the other hand.
- c. Keep your eye wide open and slowly bring your lens up to the eye looking straight ahead. Gently place the lens on the cornea. Do not press the lens against your eye.
- d. Release the eyelids slowly and blink gently.
- e. Check your vision out of that eye to ensure the lens is in place before moving around to avoid accidental loss of a misplaced lens.

Repeat this procedure for the other lens. **NOTE: IF IT IS EASIER, YOU CAN SWITCH HANDS.** There are other methods of lens placement. If the above method is difficult for you, your eyecare professional will provide you with an alternate method.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the Lens," next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
 - a. Cosmetics or oils on the lens. Clean, rinse, disinfect and place on the eye again.
 - b. The lens is on the wrong eye.
 - c. The lens may be cracked, broken or damaged. If so, do not place the lens back on your eye.

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eyecare professional.

4. Centering the Lens

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow the procedures below.

- a. Using a mirror, locate your lens.
- b. Place your index finger on the edge of your eyelid, gently push the lens toward the center of your eye. Take care not to push too hard.

5. Removing the Lens

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. Make sure with a mirror that the lens is in place.
- c. To remove the right lens, open your eyes as wide as possible and place the index finger of your right hand at the outer corner of your eyelid and look down into the palm of your left hand or into the center of a soft cloth placed on a flat surface.
- d. Keeping your eye open wide and your lens centered between your lids, pull eyelid gently toward the top of the ear.
- e. Blink once quickly.
- f. Your lens should fall out onto your hand or onto the cloth. Do not pry your lens loose or use a fingernail to remove it. If the lens does not come out, open wide and try again.
- g. Remove the other lens by following the same procedure.
- h. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING).

Note: If this method of removing your lens is difficult for you, your eyecare professional will provide you with an alternate method.

CARING FOR YOUR LENSES

(CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/LUBRICATING)

1. Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you **first clean and rinse, then disinfect** your lenses after each removal, using the care regimen recommended by your eyecare professional. **Cleaning and rinsing** are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. Failure to clean and rinse prior to disinfecting may result in incomplete lens disinfection. **Disinfecting** is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above. If you require vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure you put the lenses on and remove them while you are in your eyecare professional's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eyecare professional should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the Menicon Z™ (tisilfocon A) Contact Lens.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.
- Use the recommended system of lens care, chemical (not heat), and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eyecare professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

The lens care products listed below are recommended for use with your Menicon Z™ (tisilfocon A) Contact Lenses. See Package Insert for other products that may be used with this lens. Your eyecare professional may recommend alternate solutions that are appropriate for you to use with your Menicon Z™ (tisilfocon A) Contact Lenses. Each lens care product contains specific directions for use and important safety information, which you should read and carefully follow. Avoid the use of abrasive surfactant cleaners such as Boston®, Boston Advance®, Opti-Free® and Opti-Soak®.

Lens Care Table

Solution Purpose	Menicon/Allergan CLARIS® Gas Permeable Care System Chemical (not heat) disinfection
Cleaning	CLARIS® Cleaning and Soaking Solution
Rinsing	Lens Plus® Sterile Saline Solution or other solution recommended by your eyecare professional
Disinfection/Storage	CLARIS® Cleaning and Soaking Solution
Lubrication/Rewetting	CLARIS® Rewetting Drops
Periodic Protein Cleaning	ProFree/GP Weekly Enzymatic Cleaner

CLARIS® and Lens Plus® are trademarks of Allergan, Inc.

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- **Clean** one lens first (always the same lens first to avoid mix-ups), **rinse** the lens thoroughly with recommended rinsing solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, **disinfect** lenses using the system recommended by your eyecare professional and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the package insert or the eyecare professional for information on storage of your lenses.
- Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eyecare professional for a recommendation on how to store your lenses.
- Menicon Z™ (tisilfocon A) Contact Lenses cannot be heat (thermally) disinfected.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Replace lens case at regular intervals.
- Your eyecare professional may recommend a lubricating/rewetting solution for your use. **Lubricating/Rewetting** solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

2. Care for a Sticking (Non-Moving) Lens

If the lens sticks (stops moving), you should apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 10 minutes, you should immediately consult your eyecare professional.

3. Chemical (Not Heat) Disinfection

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eyecare professional.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution or lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

4. Lens Deposits and Use of Enzymatic Cleaning Procedure

Enzyme cleaning may be recommended by your eyecare professional. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well being of your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation. For extended wear patients in particular, enzymatic cleaning is recommended each time the lenses are removed for an overnight break. Daily wear patients have also been shown to benefit from periodic enzymatic cleaning. Your eyecare professional will recommend a schedule that is right for you. Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

5. Lens Case Cleaning and Maintenance

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Never add fresh solution to old solution since this can increase the risk of lens and lens case contamination and eye infection. You should replace lens cases at regular intervals as recommended by the lens case manufacturer or your eyecare professional.

6. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should:
FLUSH EYES IMMEDIATELY WITH TAP WATER OR FRESH STERILE SALINE SOLUTION AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYECARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eyecare professional having additional contact or spectacle lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact or spectacle lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare professional.
- It is important that you follow your eyecare professional's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eyecare professional in conjunction with you, after carefully considering and discussing your needs.

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT (multifocal or monovision)

Two common methods of using contact lenses for presbyopic vision correction include multifocal or bifocal lenses, and monovision. Like bifocal, trifocal, or progressive addition spectacles, multifocal contact lenses have separate powers for distance and near vision in each lens. This allows the wearer to use both eyes for seeing at all distances. Monovision correction entails the use of standard single vision lenses with a distance powered lens being worn on one eye and a near powered lens on the other eye.

As with any type of lens correction, there are advantages and compromises with multifocal or monovision correction. The benefit of clear near vision in straight-ahead and upward gaze that is available may be accompanied by reduced vision at certain distances or under certain lighting conditions. Some individuals, particularly those wearing monovision lenses may experience reduced depth perception. Some patients experience difficulty adapting to this. Symptoms such as mild blurring, dizziness, headaches and a feeling of slight imbalance, may last briefly or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.

During the adaptation period it is recommended that you wear these contact lenses only in familiar situations which are not visually demanding. For example, you should avoid driving an automobile until you are comfortable that your eyes have adjusted. It is recommended that you drive with multifocal or monovision correction only if you can pass the driver's license requirements with your lenses.

- Some patients will never be fully comfortable functioning in low light, such as driving at night. If this happens, you may want to discuss with your eyecare professional having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance vision is required.
- If you perform prolonged close work requiring very sharp near vision, you may need to wear spectacles over your lenses or have additional lenses prescribed specifically for this task. You should discuss your specific visual needs with your eye care professional.
- It is important that you follow your eyecare professional's advice regarding adaptation to presbyopic vision correction. During the adaptation period you should make careful note of any specific situation where you feel unable to function effectively and safely, and discuss these concerns with your eyecare professional.
- The decision to be fit with multifocal lenses or a monovision correction should be made in conjunction with your eyecare professional only after carefully considering and discussing your needs.

WEARING AND APPOINTMENT SCHEDULES

YOUR WEARING SCHEDULE SHOULD BE DETERMINED BY YOUR EYECARE PROFESSIONAL.

Since most patients initially tend to over wear contact lenses, it is important to adhere to the initial maximum wearing schedule established by your eyecare professional. In no event should your initial maximum wearing schedule exceed the schedule set forth below. Regular checkups, as determined by your eyecare professional are also extremely important.

Do not skip visits with your eyecare professional just because your lenses feel comfortable. Routine follow-up visits help prevent problems. Only a thorough examination by your eyecare professional can determine how your eyes are responding to contact lenses. Early signs of a problem can be detected and treated before you can feel them.

The maximum suggested wearing time for the Menicon Z™ (tisilfocon A) Contact Lens is:

Daily Wear (During Waking Hours)*

<u>Day</u>	<u>Hours</u>
1	4-8
2	6-10
3	8-14
4	10-15
5	12-all waking hours
6 and after	all waking hours

*If the lenses continue to be well tolerated.

Lenses should be removed daily for cleaning and disinfecting (according to lens care system instructions) before wearing.

Extended Wear (Overnight)

- It is suggested that new contact lens wearers first be evaluated on a daily wear schedule. If you are judged to be an acceptable extended wear candidate, your eyecare professional may determine an extended wear schedule appropriate for you.
- Your eyecare professional should establish an extended wear period up to 30 continuous days/29 nights that is appropriate for you. You should not wear your lenses longer than recommended by your eyecare professional, no matter how comfortable the lenses feel. Doing so increases the risk of adverse effects.
- Once the lenses are removed, your eyes should have a rest period with no lens wear of overnight or longer, as recommended by your eyecare professional.
- See **WARNINGS** for information about the relationship between wearing schedule and corneal complications and **CLINICAL RESULTS** for important information about average wear times and other study findings.

Prescribed Wearing Schedule

<u>Day</u>	<u>Wearing Time (Hours)</u>
1	_____
2	_____
3	_____
4	_____
5	_____
6 and after	_____

Appointment Schedule

Your appointments are on:

Month	Year	Time	Day	Minimum number of hours lenses to be worn at time of appointment
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_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

PATIENT/EYECARE PROFESSIONAL INFORMATION:**Eyecare Professional Information**

Eyecare Professional Name: _____

Practice Name: _____

Eyecare Professional Address: _____

Eyecare Professional Phone Number: _____

Recommended Lens Care Regimen: _____

Cleaning Solution: _____

Rinsing Solution: _____

Disinfecting Solution: _____

Lubricating Solution: _____

IMPORTANT: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYECARE PROFESSIONAL IMMEDIATELY.